

PATENT COOPERATION TREATY

"Docketed for"

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
ROBERT S. THOMAS
NELSON MULLINS RILEY & SCARBOROUGH LLP
1320 MAIN STREET, 17TH FLOOR
COLUMBIA, SC 29201

PCT

04 JUN 05
04 JUL 05

FSC

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 16139.09052		Date of mailing (day/month/year) 04 APR 2005
International application No. PCT/US04/37813		International filing date (day/month/year) 12 November 2004 (12.11.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/40; C07D 207/34 and US Cl.: 514/423; 548/537		Priority date (day/month/year) 12 November 2003 (12.11.2003)
Applicant UNIVERSITY OF SOUTH CAROLINA		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Laura L. Stockton, Ph.D. Telephone No. 703/308-1235
--	--

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/37813

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/37813

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 36

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 36 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 36 fails to provide a structure or nomenclature of a phosphodiesterase-4 inhibitor or a calcium channel blocker that can be administered to prevent or treat a cardiovascular or a respiratory disorder. Therefore, claim 36 is unsearchable.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/37813

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-35 and 37-43</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-35 and 37-43</u>	NO
Industrial applicability (IA)	Claims <u>1-35 and 37-43</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-35 and 37-43 lack an inventive step under PCT Article 33(3) as being obvious over Johnson et al. {Journal of Pharmaceutical Sciences (1979), 68(8), pages 955-958}.

Applicant claims pyrrole compounds. Johnson et al. teach pyrrole compounds that are structurally similar to the instant claimed compounds. See, for example, the compounds in the table at the bottom of page 955. The difference between the compounds of Johnson et al. and the compounds instantly claimed is that of hydrogen versus a methyl (e.g., homologues).

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in Johnson et al. with the expectation of obtaining compounds which could be useful in the pharmaceutical arts. The instant claimed compounds would have been suggested to one skilled in the art and therefore, lack an inventive step.